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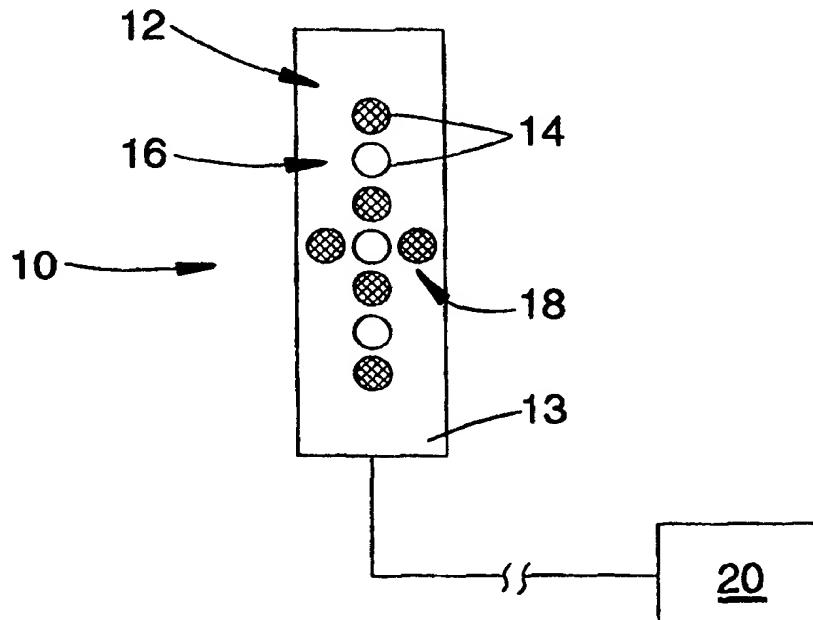
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(54) Title: SURGICAL VISUAL FEEDBACK AND EYE FIXATION METHOD AND APPARATUS

(57) Abstract

A fixation apparatus is provided that limits rotation of the ocular globe of an eye, to facilitate alignment of an instrument with the axis of astigmatism of the eye. The apparatus includes fixation target means (12) for locating in the field of view of the eye so that the eye may fixate on the target. The fixation target means includes or consists of at least one elongate component (16). Also disclosed is a corresponding method, and method and apparatus for supplying visual feedback to an operator during refractive surgery of an eye of a patient.



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SURGICAL VISUAL FEEDBACK AND EYE FIXATION METHOD AND APPARATUS

Field of the Invention

5 The present invention relates, in different aspects, to eye fixation and to the provision of visual feedback to a surgeon, during the delivery of medical laser procedures, particularly in the fields of ophthalmic surgical procedures, such as Photorefractive Keratectomy (PRK) and Laser-in-situ Keratomileusis (LASIK), or any laser based refractive correction. The invention will be described with reference to
10 these applications, though it is to be understood that other applications are envisaged.

Background Art

Most existing refractive laser delivery systems provide little feedback for the operator (typically a surgeon). Usually a crosshair graticule is superimposed through
15 the microscope optics to help the operator aim the laser beam correctly onto the cornea. A fixation target or light, such as a flashing LED, is used to ensure that the patient's eye remains correctly aligned during the surgery. However, this arrangement does not necessarily provide the best alignment of the eye and the laser beam, nor does it provide visual feedback for the operator concerning the
20 status of the eye or the laser. It may at times be necessary for the operator to move his or her attention away from the surgical field to check on instrumentation, such as the microkeratome or the laser source. The axis of astigmatism of the patient's eye is also likely to be misaligned when the patient is supine and fixating on a point of light.

Refractive errors are usually assessed when the patient is seated in an upright
25 position using structured shapes or symbols, such as letters of the alphabet. However, refractive surgery is usually performed with the patient reclining in an operating chair. It has been found that, when a patient lies recumbent, the ocular globe is liable to rotate, altering the position of the axis of astigmatism between 7°

and 16° in 25% of cases (Smith, Talamo, Assil & Petashnick, "Comparison of Astigmatic Axis in the Seated and Supine Positions", J. of Refractive & Corneal Surgery 10(6), 615 (1994)). This occurs for two reasons: i) the removal of the reference horizon, and ii) the change from binocular to monocular vision. Focussing 5 on a point of light (the flashing LED), instead of the linear horizon, does not provide a proper point of horizontal or vertical reference. The globe is therefore liable to rotate fractionally, possibly resulting in misalignment of the treatment of the eye's axis of astigmatism. The potential end result is under-treatment of the original astigmatic error or inducement of astigmatism at another axis.

10 US Patent 5,549,597 describes a method for determining the axis of astigmatism of a patient undergoing refractive surgery, so as to provide real-time alignment information for the surgical procedure. The patient is required to focus on a target such as three sets of three lines of variable line spacing, each set corresponding to a different visual acuity, and then to focus on the best resolved set 15 of lines and rotate the target until the finest line is seen most clearly. This method of determining the axis of astigmatism and aligning the surgical laser is not ideal. The patient is forced to make subjective comparisons at a highly stressful time. In addition, the globe may still rotate after the alignment has been performed, and prior to surgery.

20 An earlier configuration for determining the axis of astigmatism is described in US Patent 3,785,723, and involves rotation of an opaque disk having multiple small apertures backlit by a light source so as to resemble a set of point light sources arranged in a straight line along the diameter of the disk.

US Patent 5,442,412 discloses a patient responsive eye fixation target for use 25 in ophthalmic procedures in which respective light sources produce a ring of light and a dot of light centred on the same optical axis, but respectively closer to and further from the eye. In response to detection of a quantifiable amount of eye movement, the dot is altered in appearance, eg. by flashing or colour changes, to alert the patient that his or her eye is no longer aligned with the dot and ring.

Corresponding to the patient fixation apparatus is the apparatus used by the surgeon to view and assess the extent of fixation and the alignment of the laser beam. The surgeon views this display when looking down the surgical microscope. Current technology provides a display including a graticule or crosshair. A He-Ne beam is sometimes provided for aiming the surgical beam.

US Patent 4,870,964 provides a head-up display for use with an operating microscope during phaco-emulsification procedures. This apparatus allows the operating surgeon to view information about the status of the patient, the eye and operating equipment, such as vacuum pressure, without removing their gaze from the operating field. It does so by projecting light onto the operating field of the eye and conditioning the reflections from the cornea so that interpretable images may be viewed by the surgeon as they look down the microscope. US Patent 5,135,299 describes a similar operating microscope featuring a head-up display, produced by reflecting operational information from the scleral portion of the eye.

It is an object of the present invention, in at least one aspect, to provide an eye fixation method and apparatus that is simple and reliable, and involves minimal expectation of the patient. For particular applications, it is further preferred that the arrangement reduces the angular rotation of the ocular globe to facilitate alignment of an instrument with the axis of astigmatism.

It is an object of another aspect of the present invention to provide a surgical visual feedback method and apparatus that provides increased information to the surgeon or operator.

Summary of the Invention

According, therefore, to a first aspect of the present invention, there is provided a method for limiting the rotation of the ocular globe of an eye to facilitate alignment of an instrument with the axis of astigmatism of the eye. The method includes providing fixation target means in the field of view of the eye so that the eye may fixate on the target. The fixation target means includes or consists of at least one elongate component.

Preferably the method includes providing the fixation target means by way of light emitting means. Preferably, the light emitting means is strobed.

The present invention also provides, in its first aspect, a fixation apparatus that limits rotation of the ocular globe of an eye, to facilitate alignment of an instrument with the axis of astigmatism of the eye. The apparatus includes fixation target means for locating in the field of view of the eye so that the eye may fixate on the target. The fixation target means includes or consists of at least one elongate component.

Preferably, said fixation target means includes or consists of at least two intersecting substantially mutually perpendicular elongate components. The fixation target means may consist substantially of a cross, and/or it may include more than two elongate components arranged as a grid. The fixation target means preferably has a fixed orientation.

The fixation target means may be a light emitting means. Moreover, the or each elongate component may be defined by the light emitting means.

Preferably, the light emitting means includes a plurality of light emitting diodes (LEDs) arranged in a respective linear array to define the or each elongate component.

Preferably the apparatus includes a printed circuit board (PCB) on which the LEDs are mounted.

Preferably the apparatus is controllable to strobe the light emitting means.

The apparatus may include a pulsable power supply to strobe the light emitting means.

In its first aspect, the invention extends to laser surgery apparatus incorporating patent observable fixation apparatus as described above.

In a second aspect of the present invention there is provided a method for

supplying visual feedback to an operator during refractive surgery of an eye of a patient, including:

- 1) providing fixation target means for the eye to fixate upon;
- 2) locating the eye for viewing by viewing means while it is fixated upon said fixation target means;
- 3) generating an information display of information pertinent to said surgery and suitable for displaying visually; and
- 4) transmitting the information display to the viewing means for viewing by the operator;

10 whereby the eye and the information display may be viewed simultaneously by the operator.

Preferably the method includes updating the information display.

Preferably step 3) includes generating the information display with a controller means.

15 Preferably the controller means is a computer.

Preferably the method includes transmitting the information display to a display means and displaying the information display on the display means.

The display means may be miniature TV or LCD screen or a plurality of LEDs.

20 Preferably step 1) includes the alignment facilitating method according to the first aspect of the invention.

Preferably the viewing means includes left and right optics means, and the target is located between the left and right optics means.

Preferably the viewing means is a surgical microscope.

The invention extends to a method of performing refractive surgery on an eye of a patient, wherein visual feedback is supplied in accordance with the method of the second aspect of the invention. The refractive surgery may eg. be PRK or LASIK,

5 thermal keratoplasty, intrastromal ablation or any other surgical method that alters the refraction of the eye.

The method may be performed with any laser suitable for use in surgery that involves altering the refractive properties of the eye, e.g. an ultraviolet ablation laser, a Holmium laser, or an Erbium laser at 3 microns.

10 Preferably step 4) includes viewing said information by means of a beam splitter or plate of glass.

In its second aspect, the invention also provides an apparatus for supplying visual feedback to an operator during refractive surgery of an eye. The apparatus includes fixation target means for the eye to fixate upon, and viewing means for viewing the eye while it is fixated upon the fixation target means.

15 Controller means is provided for generating an information display, and screen means displays the said information display, for viewing by the viewing means, whereby the eye and the information display may be viewed simultaneously by the operator.

20 Preferably the apparatus includes display means for displaying the information display.

The apparatus may be provided in combination with a surgical laser and thereby comprise laser surgery apparatus.

25 The laser may be any laser suitable for use in surgery that involves altering the refractive properties of the eye, such as a ultraviolet ablation laser, a Holmium laser, an Erbium laser at 3 microns or any other appropriate laser source.

Preferably the target means is a fixation apparatus according to the first

aspect of the invention.

The display means and/or screen means may be viewed by means of a beam splitter or plate of glass.

Preferably the display means is a miniature TV or LCD screen or a plurality of
5 LEDs.

Preferably the viewing means is a surgical microscope.

Preferably the controller means is a computer.

Preferably the viewing means includes left and right optics, and the target is located between the left and right optics.

10 In the method and apparatus of the second aspect of the invention, the information may include an alert signal indicating misalignment of the patient's eye, eg. due to straying from fixation upon the fixation target means.

15 The information may pertain to one or more of: the status of the patient, the surgery or the equipment, the position of the eye or where an eye-tracker is aiming the laser.

The information may include one or more of the following elements of operational information: type of treatment, number of laser pulses required to finish, operation time remaining, patient identification and which eye is being treated, keratometry information, refraction information, and/or topographical information.

20 The information may include microkeratome status information, such as suction and blade speed readings.

Brief Description of the Drawings

In order that the invention be more fully understood, preferred embodiments will now be described, by way of example, with reference to the accompanying

drawings, in which:

Figure 1 is a schematic view of an eye fixation apparatus according to a preferred embodiment of the first aspect of the present invention;

Figure 2 is a fragmentary view illustrating a suitable location for the eye
5 fixation target; and

Figure 3 is a diagram of the layout of the principal components of an arrangement for supplying visual feedback to an ophthalmic surgeon during refractive laser eye surgery procedures, according to a preferred embodiment of the second aspect of the present invention, but preferably incorporating the embodiment
10 of Figures 1 and 2.

Preferred Embodiments

Referring to Figures 1 and 2, there is presented a schematic view of a patient's eye fixation apparatus 10 according to a preferred embodiment of the present invention. The apparatus 10 includes a fixation target in the form of a cross
15 12 formed by surface mounted light emitting diodes, LEDs 14, arranged in two linear arrays to define intersecting elongate components or axes 16, 18 perpendicular to one another. The LEDs are fixed to a printed circuit board (PCB) 13, in turn arranged on an elongate lipped substrate 15. Substrate 15 is positioned on the front of the surgical microscope 28, symmetrically between the adjacent stereo oculars 40,42, so
20 as to be clearly observable by the patient. Alternatively, cross 12 may be located elsewhere within the surgical laser, and projected to optically appear as if it is placed between the oculars of the microscope.

Substrate 15 is fixed in position on the microscope so that cross 12 has a fixed orientation. "Vertical" axis 16 of the cross 12 of LEDs 14 is longer than
25 "horizontal" axis 18, by providing several more LEDs 14 in axis 16 than axis 18. By "vertical" is meant the axis that extends normal to the lines joining the oculars. The LEDs 14 may alternatively be positioned to form any other pattern of elongate or linear elements, such as a line or a grid.

The cruciform arrangement of LEDs 14 allows the patient to better judge horizontal and vertical directions, so that the ocular globe(s) of the patient does not rotate and the axis of astigmatism is naturally aligned.

A suitable control circuit 20, of a simple form readily apparent to those skilled in the art, is provided for strobing LEDs 14 in a pre-selected, perhaps adjustable, sequence. The LEDs may, for example, flash in unison or in a more complex pattern. LEDs 14 may be of varying colours to facilitate patient concentration and gaze control. In use, the patient is required to fixate his or her gaze on the flashing cross 12, thereby preventing angular rotation of the ocular globe and misalignment of the treatment eye's axis of astigmatism. A preferred flash rate is about 1.5 Hz with a duty cycle of about 50%. The duty cycle may be adjustable, for example to allow more light during LASIK and less light during PRK.

Figure 3 is a diagram of an apparatus 22 for supplying visual feedback to an ophthalmic surgeon during refractive laser eye surgery procedures being performed on an eye 24. This apparatus is an embodiment of the second aspect of the invention. The apparatus 22 includes a surgical microscope 28', a fixation target 26, which is preferably a flashing cross 12' as in Figures 1 and 2, on microscope 28', a head-up display 30 to give the surgeon feedback regarding patient fixation, the operating conditions and other pertinent information, and an imaging device in the form of a miniaturised TV or LCD screen 32 supplied within the laser delivery head (not shown). The head-up display 30 may be produced by projecting lights onto a surface, as is known in the art, and may be displayed on screen 32. The imaging device may alternatively comprise a combination of light emitting diodes.

The apparatus 22 further includes a controller in the form of computer 34 and communications link 36 between computer 34 and screen 32. Computer 34 generates the information content (comprising information pertinent to the operation being carried out) of the head-up display 30, and transmits this content via link 36 to screen 32 to display. This content could include a pulse countdown, operation time remaining, an alert signal indicating misalignment of the patient's eye, a cross 31 indicating where the laser is currently aimed, patient information such as name or ID, treatment zone information, topographical information and any other information that

the surgeon may deem useful.

The apparatus 22 also includes a beamsplitter 38, by which the head-up display 30 is viewed. The beamsplitter 38 forms a part of the optics of the laser (not shown), for relaying this information towards oculars 40', 42' of the microscope 5 28', so that the operator may see the information when he or she looks down the microscope 28'.

Thus, in use, while the patient views (50) a suitable fixation target 26 (such as a fixation cross 12' as described above), the surgeon is able to view the patient's eye 24 (51) and the head-up display 30 (52) through the surgical microscope 28'.

Claims

1 A fixation apparatus for limiting the rotation of the ocular globe of an eye, to facilitate alignment of an instrument with the axis of astigmatism of the eye, including:

5 fixation target means for locating in the field of view of said eye so that said eye may fixate on said target;

 wherein said fixation target means includes or consists of at least one elongate component.

2 Apparatus according to claim 1 wherein said fixation target means includes or consists of at least two intersecting, substantially mutually perpendicular elongate components.

3 Apparatus according to claim 2 wherein said fixation target means consists substantially of a cross.

4 Apparatus according to claim 2 or 3 wherein one of the at least two elongate components is longer than the other.

5 Apparatus according to claim 1 wherein said fixation target means includes more than two elongate components arranged as a grid.

6 Apparatus according to any one of claims 1 to 5 wherein said fixation target means is a light emitting means.

20 7 Apparatus according to claim 6 wherein the or each said elongate component is defined by said light emitting means.

8 Apparatus according to claim 6 or 7, wherein said light emitting means includes a plurality of light emitting diodes arranged in a respective linear array to define the or each said elongate component.

9 Apparatus according to claim 8, further including a printed circuit board (PCB) on which the light emitting diodes are mounted.

10 Apparatus according to any one of claims 6 to 9, further including means to strobe said light emitting means.

5 11 Laser surgery apparatus incorporating patient observable fixation apparatus according to any one of claims 1 to 10.

12 Laser surgery apparatus according to claim 11, wherein said fixation target means is disposed in a patient observable position on a surgical microscope of said laser surgery apparatus.

10 13 Laser surgery apparatus according to claim 12 wherein said at least one elongate component is arranged in a "vertical" orientation on said surgical microscope.

14 A method for limiting the rotation of the ocular globe of an eye to facilitate alignment of an instrument with the axis of astigmatism of the eye, including
15 providing fixation target means in a field of view of said eye so that said eye may fixate on said target, wherein said fixation target means includes or consists of one elongate component.

15 16 A method according to claim 14, wherein said fixation target means includes or consists of at least two intersecting, substantially mutually perpendicular elongate components.

16 17 A method according to claim 15, wherein said fixation target means consists substantially of a cross.

17 18 A method according to claim 14, wherein said fixation target means includes more than two components arranged as a grid.

25 19 A method according to anyone of claims 14 to 17, including providing said fixation target means by way of light emitting means.

19 A method according to claim 18, wherein said light emitting means includes a plurality of light emitting diodes arranged in a respective linear array to define the or each said elongate component.

20 A method according to claim 18 or 19, further including strobing
5 of said light emitting means.

21 Apparatus for supplying visual feedback to an operator during refractive surgery of an eye, including:

fixation target means for said eye to fixate upon;

viewing means for viewing said eye while it is fixated upon said
10 fixation target means;

controller means for generating an information display; and

screen means for displaying said information display for viewing
by said viewing means;

whereby said eye and said information display may be viewed
15 simultaneously by said operator.

22 Apparatus according to claim 21, further including display means for displaying said information display.

23 Apparatus according to claim 21 or 22, wherein said fixation target means includes or consists of at least one elongate component.

20 24 Laser surgery apparatus, including a surgical laser and apparatus for supplying visual feedback during laser surgery performed on an eye with the laser, which latter apparatus is according to claim 21, 22 or 23.

25 Apparatus according to any one of claims 21 to 24, wherein said screen means is a miniature TV or LCD screen or a plurality of LEDs.

26 Apparatus according to any one of claims 21 to 25, wherein said viewing means is a surgical microscope.

27 Apparatus according to any one of claims 21 to 26, wherein said controller means is a computer.

5 28 Apparatus according to any one of claims 21 to 27, wherein said information includes an alert signal indicating misalignment of the patient's eye eg. due to straying from fixation upon said fixation target means.

10 29 Apparatus according to any one of claims 21 to 28, wherein said information pertains to one or more of: the status of the patient, the surgery, the equipment, the position of the eye, or where an eye-tracker is aiming the laser.

15 30 Apparatus according to any one of claims 21 to 29 wherein said information includes one or more of the following elements of operational information: type of treatment, number of laser pulses required to finish, operation time remaining, patient identification and which eye is being treated, keratometry information, refraction information, and/or topographical information.

31 A method for supplying visual feedback to an operator during refractive surgery of an eye of a patient, including:

- 1) providing fixation target means for said eye to fixate upon;
- 2) locating said eye for viewing by said operator by means of viewing means while the eye is fixated upon said fixation target means;
- 3) generating an information display of information pertinent to said surgery and suitable for displaying visually; and
- 4) transmitting said information display to said viewing means for viewing by said operator;

25 whereby said eye and said information display may be viewed

simultaneously by said operator.

32 A method according to claim 31, including updating said information display.

33 A method according to claim 31 or 32, further including
5 generating said information display with a controller means.

34 A method according to claim 33, further including transmitting said information display to a display means and displaying said information display on said display means.

35 The method of any one of claims 31 to 34, wherein said fixation
10 target means provided includes or consists of at least one elongate component.

36 A method of performing refractive surgery on an eye of a patient
wherein visual feedback is supplied in accordance with any one of claims 31 to 35.

37 A method according to any one of claims 31 to 36, wherein said
information includes an alert signal indicating misalignment of the patient's eye eg.
15 due to straying from fixation upon said fixation target means.

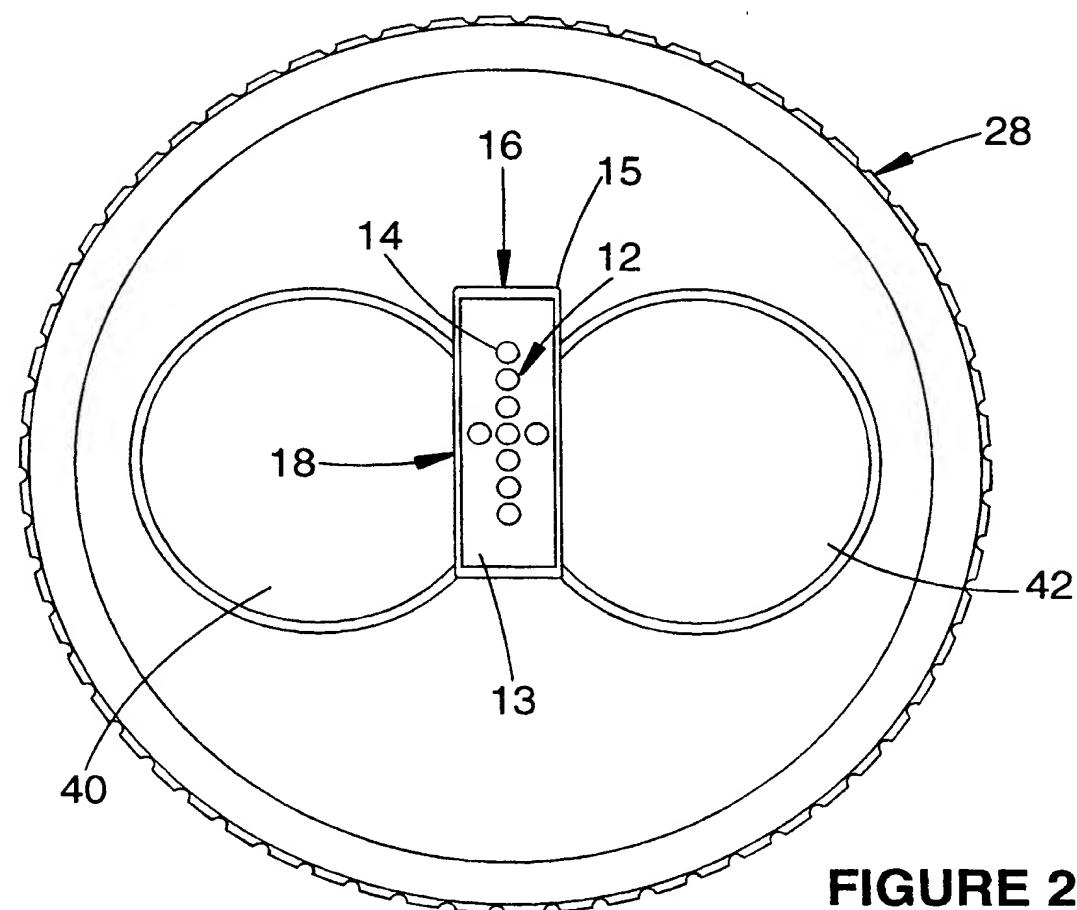
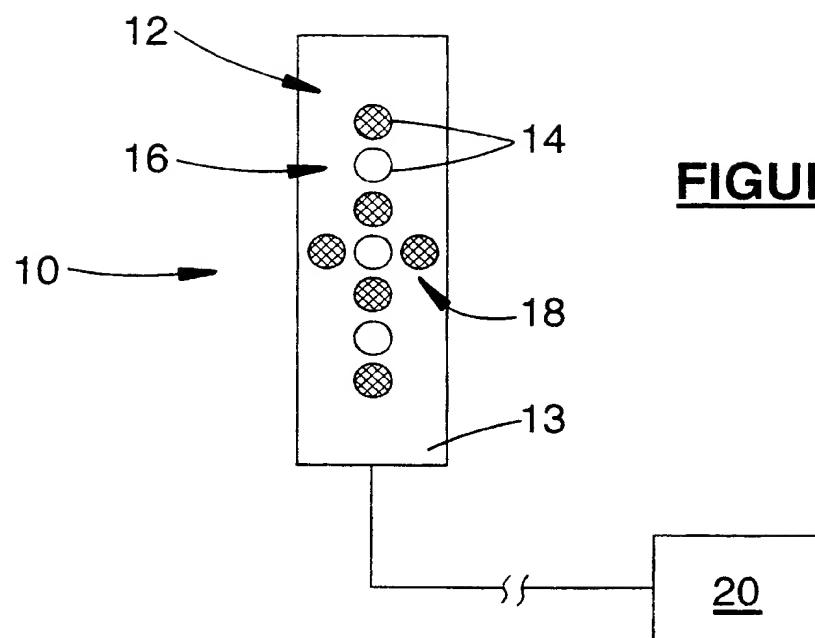
38 A method according to any one of claims 31 to 37, wherein said
information pertains to one or more of: the status of the patient, the surgery, the
equipment, the position of the eye, or where an eye-tracker is aiming the laser.

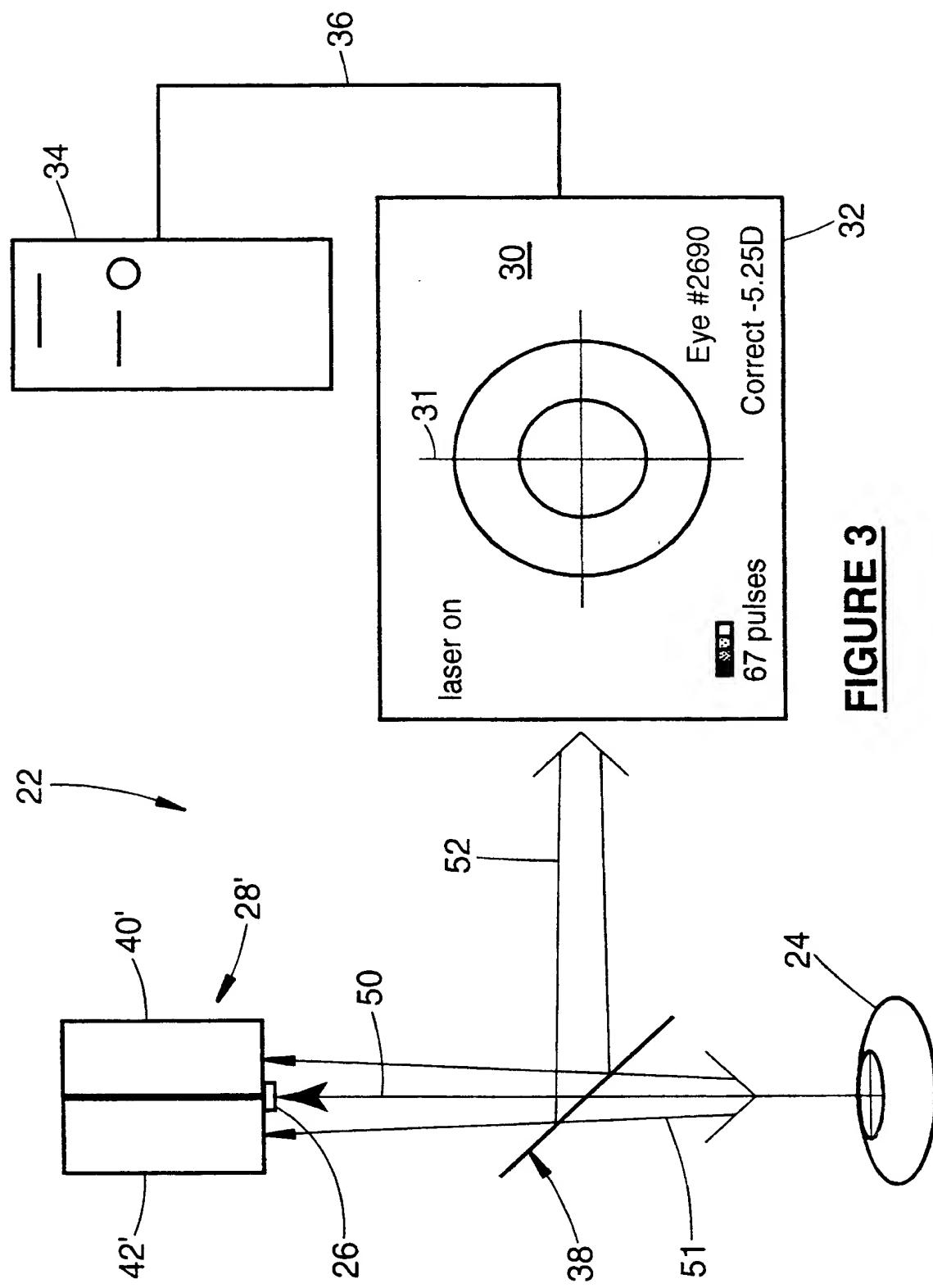
39 A method according to any one of claims 31 to 38 wherein said
20 information includes one or more of the following elements of operational
information: type of treatment, number of laser pulses required to finish, operation
time remaining, patient identification and which eye is being treated, keratometry
information, refraction information, and/or topographical information.

40 An apparatus according to any one of claims 1 to 13 or 21 to 30, wherein said fixation target means has a fixed orientation.

41 A method according to any one of claims 14 to 20 or 31 to 39 wherein said fixation target means is provided so as to have a fixed orientation.

1/2





INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00665

A. CLASSIFICATION OF SUBJECT MATTER		
Int Cl ⁶ : A61B 3/02 A61F 9/007		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
KEYWORDS		
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C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 4993825 A (ABE et al.) 19 February 1991 figure 3; column 2, lines 34-57 as above	1-20, 40-41 23,35
X,D Y	US 5549597 A (SHIMMICK et al.) 27 August 1996 abstract; figures 1,5,10; column 5, line 53 - column 6, line 4; column 6, line 58 - column 7, line 15 as above	1,2,11,12,14,15 23,35
X Y	US 4536065 (SHEINGORN) 20 August 1985 figure 1; claims as above	1-4,14-16 23,35
<input checked="" type="checkbox"/>	Further documents are listed in the continuation of Box C	<input checked="" type="checkbox"/> See patent family annex
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Date of the actual completion of the international search 24 September 1999	Date of mailing of the international search report - 7 OCT 1999	
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International application No. PCT/AU 99/00665

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 164981 A (THE UNIVERSITY COURT OF THE UNIVERSITY OF GLASGOW) 18 December 1985 abstract; figure 1 as above	1-4,14-16 23,35
X,D	US 5135299 A (KITAJIMA et al.) 4 August 1992 abstract; figures; column 4, line 65- column 5, line 22	21,22,24-27, 29-34,36, 38-41
Y	as above	23,35
X,D	US 4870964 A (BAILEY, Jr. et al.) 3 October 1989 whole document	21,22,24-27 29-34,36, 38-41
Y	as above	23,35
Y	US 4678297 A (ISHIKAWA et al.) 7 July 1987 column 5, lines 29-31; claim 9	28,37
Y	WO 98/00078 A (LIFE SCIENCE RESOURCES LTD) 8 January 1998 claims 5-7	28,37

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 99/00665**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. Claims 1-20 directed to a fixation target with at least one elongate component for limiting the rotation of the ocular globe of an eye.
2. Claims 21-41 directed to an apparatus for supplying visual feedback to an operator during refractive surgery of an eye.

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU 99/00665

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member
US	4993825	JP	2150202	
EP	164981	US	4737024	
US	5135299	JP	3185416	

END OF ANNEX